510(k) Summary

APR 2 5 2013

Date of Summary: April 24, 2013

Submitted by:

Submitter:	Caldera Medical, Inc.
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Contact:	Vicki Gail, Manager QA/RA
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Device Information:

Trade Name: Vertessa Lite Y-Mesh

Classification: Class II, Product Code: OTO, Surgical Mesh, Gynecologic, 21 CFR 878.3300, General and Plastic Surgery

Predicates: Alyte Y-Mesh Graft (K101722), C.R. Bard, Inc.
Restorelle Y-Mesh (K112322), Coloplast A/S

Description of Device:
Vertessa Lite Y-Mesh is designed to be used in women suffering from uterine or vaginal vault prolapse and is implanted or affixed using suture of the surgeon's choice. Vertessa Lite Y-Mesh is provided sterile and is comprised of non-absorbable macroporous monofilament polypropylene warp knit blue mesh in a y-shape design.

Intended Use of Device:
Vertessa Lite Y-Mesh may be used as a bridging material for sacrocolposuspension/sacrocolpopexy (laparotomy; laparoscopic, or robotically-assisted approach) where surgical treatment for vaginal vault prolapse is warranted.

Technological Characteristics
Vertessa Lite Y-Mesh a modification of the predicate mesh devices, Alyte Y-Mesh Graft (K101722) by C.R. Bard, Inc. and Restorelle Y-Mesh (K112322) by Coloplast A/S. The device design is a Y-shape configuration, which is similar to that of the predicate mesh devices, has a similar intended use as that of the predicate devices and does not change the fundamental scientific technology of the predicate devices.

Performance Summary
In accordance with the *FDA's Guidance for Industry and FDA Staff "Format for Traditional and Abbreviated 510(k)'s* the results of non-clinical bench, simulated use, surgeon feedback and validation testing has shown the Vertessa Lite Y-Mesh device to be substantially equivalent to that of the predicate device in its intended use, function, technological characteristics and performance.

In accordance with the *FDA's Guidance for the Preparation of a Premarket Notification Application for Surgical Mesh,* the following mesh characteristics were assessed: mesh thickness, mesh knit characteristics, pore size, mesh density, tensile strength, mesh stiffness, flexural rigidity, tear resistance, burst strength, suture pullout and Pyrogen levels.

Vertessa Lite Y-Mesh has passed all biocompatibility testing as indicated per the FDA guidance documents, *FDA Device Advice, Guidance Documents (Medical Device and Radiation Emitting Product), 3. Biocompatibility* and FDA *Blue Book Memorandum #G95-1 Entitled "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing".*

In accordance with the FDA Guidance, *Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry, FDA, FDA Device Advice, Guidance Documents (Medical Device and Radiation Emitting Product), 4. Labeling* and FDA Consensus standard, *ASTM F-1980-07, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices,* Vertessa Lite Y-Mesh has passed all testing requirements in terms of aging, shelf life, transportation and sterilization.

Bench and failure mode testing demonstrates that the performance of Vertessa Lite Y-Mesh is substantially equivalent to that of the predicate devices, Alyte Y-Mesh Graft (K101722) by C.R. Bard and Restorelle Y-Mesh (K112322) by Coloplast A/S.

Summary of Substantial Equivalence
Vertessa Lite Y-Mesh has demonstrated that it is substantially equivalent to that of the predicate devices, Alyte Y-Mesh Graft, (K101722), a product of Bard Medical and Restorelle Y-Mesh (K112322) a product of Coloplast A/S.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 25, 2013

Caldera Medical, Inc.
% Ms. Vicki Gail
QA/RA Manager
5171 Clareton Drive
AGOURA HILLS CA 91301

Re: K123028
Trade/Device Name: Vertessa™ Lite Y-Mesh
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTO
Dated: April 16, 2013
Received: April 18, 2013

Dear Ms. Gail:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

CALDERA MEDICAL

Statement of Indications For Use

Indications For Use

510 (k) Number (if known): #K123028

Device Name: Vertessa™ Lite Y-Mesh

Indications for Use:

Vertessa™ Lite Y-Mesh may be used as a bridging material for sacrocolposuspension/sacrocolpopexy (laparotomy; laparoscopic, or robotically-assisted approach) where surgical treatment for vaginal vault prolapse is warranted.

Prescription Use --X-- AND/OR Over the Counter Use_____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123028